

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF NEVADA

3 BARBARA HEINRICH and GREGORY  
4 HEINRICH,

5 Plaintiffs

6 v.

7 ETHICON, INC.; ETHICON LLC; and  
8 JOHNSON & JOHNSON,

9 Defendants

Case No.: 2:20-cv-00166-APG-VCF

**Order Granting in Part the Defendants'  
Motion to Exclude Opinions of Daniel  
Elliott**

**[ECF No. 101]**

10 This case was part of multidistrict litigation (MDL) assigned to the United States District  
11 Court for the Southern District of West Virginia concerning the use of transvaginal surgical mesh  
12 to treat stress urinary incontinence (SUI). Plaintiff Barbara Heinrich alleges that she suffered  
13 injuries after having the TVT-SECUR (TVT-S) product implanted. The TVT-S was designed  
14 and manufactured by defendants Johnson & Johnson and Ethicon, Inc. ECF No. 4 at 3.

15 The defendants move to preclude Dr. Daniel Elliott from: (1) testifying that non-synthetic  
16 mesh procedures, such as autologous slings and Burch colposuspension, are safer alternatives to  
17 TVT-S; (2) comparing TVT-S with other medical devices; (3) testifying that a lighter-weight,  
18 larger-pore mesh would have been a safer alternative; (4) criticizing Ethicon's research and  
19 testing; and (5) criticizing Ethicon's physician outreach and training.

20 The parties are familiar with the facts, so I recount them here only as necessary to resolve  
21 the motion. I grant the motion in part.

22 ////

23 ////

1 **I. ANALYSIS**

2 Federal Rule of Evidence 702 governs the admissibility of Dr. Elliott’s opinions. Under  
3 Rule 702, a witness “who is qualified as an expert by knowledge, skill, experience, training, or  
4 education may testify in the form of an opinion or otherwise if”:

- 5 (a) the expert’s scientific, technical, or other specialized knowledge will  
6 help the trier of fact to understand the evidence or to determine a fact in  
7 issue;  
8 (b) the testimony is based on sufficient facts or data;  
9 (c) the testimony is the product of reliable principles and methods; and  
10 (d) the expert has reliably applied the principles and methods to the facts  
11 of the case.

12 To be admissible, expert testimony thus must be both relevant and reliable. “Expert opinion  
13 testimony is relevant if the knowledge underlying it has a valid connection to the pertinent  
14 inquiry. And it is reliable if the knowledge underlying it has a reliable basis in the knowledge  
15 and experience of the relevant discipline.” *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010)  
16 (quotation omitted), *as amended* (Apr. 27, 2010). Medical expert testimony should be admitted  
17 “if physicians would accept it as useful and reliable, but it need not be conclusive because  
18 medical knowledge is often uncertain.” *Id.* (quotation omitted). Where there is a sufficient  
19 foundation for the testimony, it is up to the jury to evaluate the expert’s credibility. *Id.* at 565-66.

20 The proponent of expert testimony “has the burden to establish its admissibility.” *United*  
21 *States v. 87.98 Acres of Land More or Less in the Cnty. of Merced*, 530 F.3d 899, 904 (9th Cir.  
22 2008). But Rule 702’s inquiry is “flexible,” and should be applied in favor of admitting the  
23 evidence. *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1232 (9th Cir. 2017) (quotation  
omitted). “Shaky but admissible evidence is to be attacked by cross examination, contrary  
evidence, and attention to the burden of proof, not exclusion.” *Primiano*, 598 F.3d at 564.

////

1           **A. Alternative Procedures**

2           The defendants argue that Dr. Elliott should not be allowed to opine that autologous  
3 slings or Burch colposuspensions are safer alternative procedures for the treatment of SUI  
4 because these are alternative surgical procedures, not alternative safer designs of the defendants'  
5 medical device, and so his testimony on this point is irrelevant. The defendants assert that  
6 identifying safer alternative procedures takes issue with Heinrich's implanting surgeon's  
7 decision to recommend the TVT-S over these other procedures, but does not reflect whether  
8 there is a safer alternative design for the TVT-S.

9           Heinrich responds that Dr. Elliott's opinions are relevant to whether the TVT-S was  
10 unreasonably dangerous because the comparison with alternative procedures may show that the  
11 TVT-S was more dangerous than the ordinary user would contemplate given other efficacious  
12 options with fewer complications. Heinrich also contends that Dr. Elliott's opinions are relevant  
13 to her negligence claim to "explain to the jury that women with [SUI] are not restricted to mesh  
14 devices and that synthetic slings are not the most successful procedures for SUI." ECF No. 107  
15 at 5. She also asserts that the opinions are relevant to her request for punitive damages because  
16 "[m]any doctors who used non-mesh procedures later used synthetic mesh devices after  
17 manufacturers were willing to pay the doctors for 'teaching' the use of their products." *Id.*  
18 Finally, Heinrich contends that the evidence is relevant to rebut Ethicon's assertions that the  
19 TVT-S was the safest and most effective treatment for SUI.

20           To establish a strict products liability claim under Nevada law, a plaintiff must show:  
21 "1) the product had a defect which rendered it unreasonably dangerous, 2) the defect existed at  
22 the time the product left the manufacturer, and 3) the defect caused the plaintiff's injury."  
23 *Fyssakis v. Knight Equip. Corp.*, 826 P.2d 570, 571 (Nev. 1992). A product is unreasonably

1 dangerous if it fails to perform “in the manner reasonably to be expected in light of [its] nature  
2 and intended function” and “was more dangerous [than] would be contemplated by the ordinary  
3 user having the ordinary knowledge available in the community.” *Allison v. Merck & Co., Inc.*,  
4 878 P.2d 948, 952 (Nev. 1994) (quotation omitted). Evidence that the product in question  
5 “lacked adequate safety features or that a safer alternative design was feasible at the time of  
6 manufacture will support a strict liabilities claim.” *Fyssakis*, 826 P.2d at 572. However, proving  
7 that an alternative safer design existed is not required for the plaintiff to prove her case. *Ford*  
8 *Motor Co. v. Trejo*, 402 P.3d 649, 655-57 (Nev. 2017) (en banc).

9 Heinrich does not argue that Dr. Elliott should be allowed to testify that the Burch  
10 procedure or autologous slings are feasible alternative designs for the TVT-S product. She thus  
11 does not appear to contest Judge Goodwin’s analysis in *Mullins v. Johnson & Johnson*:

12 Evidence that a surgical procedure should have been used in place of a device is  
13 not an alternative, feasible design in relation to the TVT. Whether an alternative  
14 procedure could have been performed without the use of the TVT does nothing to  
15 inform the jury on the issue of an alternative, feasible design for the TVT.  
16 Instead, alternative surgeries or procedures raise issues wholly within the context  
17 of what a treating physician has recommended for patients based on the individual  
needs and risk factors associated with individual patients. In other words,  
alternative surgeries or procedures concern the medical judgment of the doctors  
who use TVT devices to treat stress urinary incontinence (“SUI”); other surgeries  
or procedures do not inform the jury on how the TVT’s design could have  
feasibly been made safer to eliminate the risks that caused the plaintiff’s injuries.

18 236 F. Supp. 3d 940, 943 (S.D. W. Va. 2017) (emphasis omitted). Because Heinrich bears the  
19 burden of showing Dr. Elliott’s testimony is admissible, and she does not argue that it is  
20 admissible for the purpose of showing alternative feasible designs, Dr. Elliott’s testimony about  
21 the alternative procedures is inadmissible to show alternative feasible safer designs of mesh  
22 devices existed.

23 ////

1 Dr. Elliott's testimony about other procedures also is not relevant to whether the TVT-S  
2 is unreasonably dangerous or whether the defendants were negligent because it takes issue with  
3 Dr. Hsieh's choice of treatment. Even if there was some relevance to this evidence, the  
4 probative value is substantially outweighed by the danger of unfair prejudice, confusion, and  
5 waste of time. Fed. R. Evid. 403. This evidence would result in exploration of whether Dr.  
6 Hsieh made the proper medical choice among available alternatives for Heinrich's particular  
7 circumstances, instead of whether the defendants' product is unreasonably dangerous for its  
8 intended use or the defendants were negligent. *Mullins*, 236 F. Supp. 3d at 943.

9 Heinrich does not explain how the alternative procedures are relevant to punitive  
10 damages. To the extent the defendants paid doctors to use their product over other options, that  
11 does not make admissible Dr. Elliott's opinion that these other procedures are safer alternatives.

12 However, Dr. Elliott's opinions may be relevant to rebut the defendants' evidence at trial.  
13 Heinrich notes that the defendants and their experts often tout TVT-S as the "gold standard" for  
14 treating SUI while it was on the market. Evidence that other available procedures were just as  
15 efficacious without the attendant alleged complications is relevant to rebut that testimony.  
16 Consequently, Dr. Elliott's testimony may be admissible if the defendants open the door at trial.  
17 I therefore grant in part and deny in part this portion of the defendants' motion.

#### 18 **B. Comparing TVT-S to Other TVT Devices**

19 The defendants argue that Dr. Elliott should not be allowed to opine that the TVT, TVT-  
20 O, or other mesh devices were safer alternative designs to the TVT-S because he opined that all  
21 of those devices were unsafe due to the use of polypropylene mesh. Heinrich responds that Dr.  
22 Elliott's opinions that the other TVT products are unsafe does not mean he should be precluded  
23 from testifying that the TVT-S was even more dangerous.

1 The fact that Dr. Elliott opines that all polypropylene mesh devices are unsafe “does not  
2 preclude him from comparing or ranking such products.” *Wiltgen v. Ethicon, Inc.*, No. 12-CV-  
3 2400, 2017 WL 4467455, at \*5 (N.D. Ill. Oct. 6, 2017). The defendants’ critique goes to the  
4 weight of this evidence, not its admissibility, and is better addressed through cross examination  
5 than exclusion. I therefore deny this portion of the defendants’ motion.

6 **C. Lighter Weight, Larger Pore Mesh**

7 The defendants argue that Dr. Elliott should not be allowed to testify that a lighter-  
8 weight, larger-pore mesh would have been safer because he has no reliable basis to offer this  
9 opinion.<sup>1</sup> The defendants contend Dr. Elliott has not conducted studies to back up his opinion;  
10 he has never treated someone with SUI with a lighter-weight, larger-pore mesh; and he cites no  
11 basis for his statement that the literature and medical data show this type of mesh would provide  
12 better results with fewer complications for the treatment of SUI (as opposed to the treatment of  
13 hernia and prolapse).

14 Heinrich responds that Dr. Elliott is qualified to opine that the small-pore, heavy-weight  
15 mesh renders the TVT-S defective due to the complications it causes. She contends that “Dr.  
16 Elliott is not required to testify to a reasonable degree of probability that if Ethicon used and  
17 tested a lighter weight, smaller pore mesh in the TVT-S that it would be a safer alternative  
18 design. However, Dr. Elliott may opine that Ethicon may have made the TVT-S safer had it used  
19 and tested the mesh, but declined to do so for reasons other than the safety and efficacy of the  
20 TVT-S.” ECF No. 107 at 12.

---

21  
22  
23 <sup>1</sup> The defendants do not challenge in this motion Dr. Elliott’s opinions that smaller-pore, heavier-  
weight mesh causes complications such as chronic inflammation, bridging fibrosis, scar  
formation, and pain. ECF No. 101-1 at 22-23.

1 In his report, Dr. Elliott states that “there is a scientific consensus that synthetic meshes  
2 that are low-weight, large-pore, high porosity, monofilament, and capable of maintaining their  
3 elasticity under load have better results with fewer complications.” ECF No. 101-1 at 12.  
4 However, he relied on meshes used in the treatment of hernias and pelvic organ prolapse, not in  
5 the treatment of SUI. *Id.* Judge Goodwin reserved ruling on whether Dr. Elliott’s expert  
6 testimony about alternative designs regarding pore size and mesh weight was reliable. ECF No.  
7 101-2 at 5. Judge Goodwin stated that Dr. Elliot’s experience was “the lynchpin” of his  
8 testimony regarding “non-SUI mesh studies as they relate to meshes used in the treatment of  
9 SUI.” *Id.*

10 Although Judge Goodwin identified Dr. Elliott’s experience as the lynchpin to his  
11 testimony’s admissibility on this issue, Heinrich has not pointed to any evidence of Dr. Elliott’s  
12 experience that would bridge the gap between the use of meshes with different pore sizes and  
13 weight in the treatment of other medical conditions in other parts of the body and the use in  
14 treatment of SUI in the vagina. At his deposition, Dr. Elliott stated he was unaware of any  
15 studies showing that a larger-pore, lighter-weight mesh works as well or better than TVT  
16 products, nor could he identify a study that showed that this mesh would have fewer  
17 complications than the mesh used in the TVT-S. ECF No. 101-3 at 11, 14. Heinrich thus has not  
18 shown Dr. Elliott’s review of the medical literature reliably supports his opinion and she has  
19 offered no evidence that his experience does either. I therefore grant this portion of the  
20 defendants’ motion and exclude Dr. Elliott’s opinion that a larger-pore, lighter-weight mesh was  
21 a feasible alternative design to the TVT-S that would have resulted in fewer complications.

22 Dr. Elliott criticizes the defendants for not conducting the studies that would fill this  
23 knowledge gap because Ethicon produced larger-pore, lighter-weight mesh for other treatments,

1 but chose not to investigate that option for its TVT device for marketing, as opposed to safety,  
2 reasons. *Id.* at 13-14. Heinrich contends, in a single unsupported sentence, that Dr. Elliott should  
3 be allowed to offer this opinion. But she does not explain why or what relevance it has to any  
4 claim or defense in this action. To the extent it relates to what testing he believes the defendants  
5 should have done, I address that issue below.

#### 6 **D. Critiques of Ethicon's Research and Testing**

7 The defendants argue that Dr. Elliott should not be able to critique Ethicon for not  
8 performing testing or conducting studies. The defendants contend that a lack of studies or  
9 research does not show a defect in the product. They also assert that Dr. Elliott is not qualified  
10 to testify about what testing a manufacturer should perform before distributing a medical device,  
11 he could not support his opinion, and there is no evidence as to what the recommended studies  
12 would have shown.

13 Heinrich concedes that Dr. Elliott is not qualified to opine on the legal adequacy of the  
14 defendants' research and testing. ECF No. 107 at 14-15. And the defendants agree that Dr.  
15 Elliott may testify about how any studies they actually conducted impacted his findings. ECF  
16 No. 112 at 9. But the parties dispute whether Dr. Elliott may testify about how the defendants'  
17 lack of testing impacts his opinions, and may factually describe the testing the defendants did not  
18 conduct.

19 Dr. Elliott may testify about any tests or studies the defendants or other third parties  
20 conducted and how those tests or studies impact his decision. *See Herrera-Nevarez by Springer*  
21 *v. Ethicon, Inc.*, No. 12 C 2404, 2017 WL 3381718, at \*7 (N.D. Ill. Aug. 6, 2017) (allowing Dr.  
22 Elliott's testimony "regarding whether and why, as a clinician, studies and testing conducted by  
23 defendants or others are sufficient to impact his opinions regarding the TVT-O or similar

1 devices” (emphasis omitted)). However, Dr. Elliott cannot comment on the defendants’ failure  
2 to conduct certain testing because he is not qualified to opine on what testing a manufacturer  
3 should do, and the “factual underpinnings” of a lack of testing “would be nothing more than a  
4 summary of corporate documents from an expert witness, which the MDL Court rejected.”  
5 *Wiltgen*, 2017 WL 4467455, at \*6. I therefore grant this portion of the defendants’ motion, with  
6 the caveat that Dr. Elliott may testify about how any testing the defendants actually conducted  
7 impacts his opinions.

#### 8 **E. Critiques of Ethicon’s Physician Outreach and Training**

9 The defendants argue that Dr. Elliott should be precluded from opining that they failed to  
10 properly train physicians on how to implant the TVT-S. The defendants contend that this  
11 opinion is irrelevant in this case because no one has opined that Heinrich’s physician, Dr. Hsieh,  
12 improperly implanted the device. Alternatively, the defendants argue that Dr. Elliott is not  
13 qualified to opine about the level of training a manufacturer is required to provide. Heinrich  
14 responds that the defendants undertook the duty of training Dr. Hsieh and their failure to do so  
15 increased the risk to her.<sup>2</sup>

16 Heinrich has not pointed to evidence that anyone is going to opine that Dr. Hsieh was  
17 inadequately trained or that he improperly implanted the TVT-S. Consequently, whether the  
18 defendants failed to train Dr. Hsieh is irrelevant to the issues in this case because there is no  
19 evidence that any failure to train led to Heinrich’s injuries. Heinrich also has not pointed to  
20 evidence that Dr. Elliott is qualified to opine on what training a medical device manufacturer  
21 should provide to physicians. I therefore grant this portion of the defendants’ motion and  
22

---

23 <sup>2</sup> Heinrich asserts that this evidence may be admissible on rebuttal. The defendants do not  
respond to that argument. I reserve that issue for trial should it arise.

1 exclude Dr. Elliott's opinions regarding the defendants' allegedly inadequate training of  
2 physicians.

3 **II. CONCLUSION**

4 I THEREFORE ORDER that the defendants' motion to exclude certain opinions of Dr.  
5 Daniel Elliott (**ECF No. 101**) is **GRANTED in part**.

6 DATED this 4th day of June, 2021.



---

ANDREW P. GORDON  
UNITED STATES DISTRICT JUDGE